

## **REMARKS**

### **I. Introduction**

Claims 7 and 9 to 13 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

### **II. Rejection of Claims 7, 12 and 13 Under 35 U.S.C. § 102(e)**

Claims 7, 12 and 13 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 5,744,031 ("Bene"). Applicants respectfully submit that Bene does not anticipate the present claims for the following reasons.

Claim 7 relates to a dialysis machine. Claim 7 recites that the dialysis machine includes a dialyzer and a semipermeable membrane dividing the dialyzer into a blood chamber and a dialysis fluid chamber, the blood chamber having an inlet and an outlet, and the dialysis fluid chamber having an inlet and an outlet. Claim 7 also recites that the dialysis machine includes an arterial blood line connected to the inlet of the blood chamber, and a venous blood line connected to the outlet of the blood chamber. Claim 7 also recites that the dialysis machine includes a dialysis fluid inlet line connected to the inlet of the dialysis fluid chamber, and a dialysis fluid outlet line connected to the outlet of the dialysis fluid chamber. Claim 7 has been amended herein without prejudice to recite that the dialysis machine includes a first device for determining at least a first measured or predetermined flow rate and a second measured or predetermined flow rate selected from the group of a blood flow rate  $Q_b$  through the blood chamber, a dialysis fluid flow rate  $Q_d$  through the dialysis fluid chamber, and an ultrafiltration rate  $Q_f$ . In addition, claim 7 has been amended herein without prejudice to recite that the dialysis machine includes a computer unit configured to establish at least one of a clearance and a dialysance at the first flow rate and determine the at least one of the clearance and the dialysance at the second flow rate on the basis of the at least one of the clearance and a dialysance established at the first flow rate. These amendments are made primarily to improve the grammar and clarity of the claim language. In addition, support for this amendment can be found at page 5, lines 29 to 33 of the Specification which states that "the clearance and/or dialysance can be estimated throughout the course of the entire dialysis treatment on the basis

of the clearance and/or dialysance established at a given dialysis fluid rate, blood flow rate or ultrafiltration rate.” Emphasis added. Furthermore, the Specification states at page 5, lines 1 to 10 that “the clearance and/or dialysance established at the predetermined dialysis fluid rate, blood flow rate and/or ultrafiltration rate can be measured [or, if] the clearance and/or dialysance established at the given dialysis fluid rate, blood flow rate or ultrafiltration rate is known, it need not be measured.”

Bene purports to relate to an artificial kidney that includes measurement structure for measuring at least one physical characteristic of a fresh dialysis liquid and of used liquid. According to Bene, the measurement structure are disposed in a line portion common to a branch circuit to the feeder line of fresh dialysis liquid and to a branch circuit to the discharge line for the used liquid. Bene states that an occluding structure permits the liquid to circulate exclusively in one or the other branch circuit, and that, due to this arrangement, it is possible to obtain the value of the physical characteristics of a patient's blood by calculation as frequently as desired, and to adjust the operation of the kidney permanently to a therapeutic objective set by the physician.

It is respectfully submitted that Bene does not anticipate the present claims for at least the reason that Bene does not disclose, or even suggest, all of the limitations recited in claim 7. For instance, it is respectfully submitted that Bene fails to disclose, or even suggest, a computer unit configured to establish at least one of a clearance and a dialysance at a first flow rate and determine the at least one of the clearance and the dialysance at a second flow rate on the basis of the at least one of the clearance and a dialysance established at the first flow rate, as recited in claim 7. As set forth above, the Specification states at page 5, lines 29 to 33 that “the clearance and/or dialysance can be estimated throughout the course of the entire dialysis treatment on the basis of the clearance and/or dialysance established at a given dialysis fluid rate, blood flow rate or ultrafiltration rate.” Emphasis added. Furthermore, the Specification states at page 5, lines 29 to 33 that “only a single measurement is necessary to be able to monitor the course of the clearance and/or dialysance over time.” Emphasis added.

In contrast, Bene describes that “[m]easurements are then taken in the dialysis liquid during the whole treatment session by means of the sensors 27.” Col. 6, lines 45 to 47. Bene also describes that “the signals delivered by the sensors 27 are supplied to the computing and control unit 26 which controls the artificial kidney

according to the parameters which it calculates, such as certain characteristic values of the blood (the concentration of ionized substances, of bicarbonate for example) as well as the performance of the artificial kidney (dialysance, clearance for a given substance) and according to the data which are supplied to it by an operator prior to the treatment session, such as the duration T of the session, the flow rates of the blood QB and of the dialysis liquid QD, the desired loss of weight WL, the desired concentration [A], [B], [C] of electrolytes A, B, C in the blood, and in particular, the desired clearance of urea KUR.” Col. 5, line 65 to col. 6, line 11. Thus, Bene merely describes a method by which a clearance or dialysance may be calculated using measured conductivity values at a given flow rate. In the event that a flow rate is changed, Bene teaches that the clearance or dialysance is re-calculated by first re-measuring the conductivity values at the new flow rate and then recalculating the clearance or dialysance on the basis of the re-measured conductivity values. This is in total contradiction to claim 7, which recites that the computer unit determines the clearance and/or the dialysance at the second flow rate on the basis of the clearance and/or the dialysance established at the first flow rate.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Bene does not disclose, or even suggest, all of the limitations recited in claim 7.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not

enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a “basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art.” See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Bene does not anticipate claim 7. As for claims 12 and 13, which depend from claim 7 and therefore include all of the limitations of claim 7, it is respectfully submitted that Bene does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 7.

### **III. Rejection of Claims 9 to 11 Under 35 U.S.C. § 103(a)**

Claims 9 to 11 were rejected under 35 U.S.C. § 103(a) as unpatentable over Bene. It is respectfully submitted that Bene does not render obvious claims 9 to 11 for the following reasons.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As stated above, it is respectfully submitted that Bene does not disclose, or even suggest, all of the limitations recited in claim 7. For example, it is respectfully submitted that Bene does not disclose, or even suggest, a computer unit configured to establish at least one of a clearance and a dialysance at the first flow rate and determine the at least one of the clearance and the dialysance at the second flow rate on the basis of the at least one of the clearance and a dialysance established at the first flow rate, as recited in claim 7.

As for claims 9 to 11, each of which ultimately depend from claim 7 and therefore include all of the limitations of claim 7, it is respectfully submitted that Bene does not render unpatentable these dependent claims for at least the same reasons given above in support of the patentability of claim 7. In re Fine, supra (any claim that depends from a non-obvious independent claim is non-obvious).

#### IV. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

KENYON & KENYON

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By: 

Thomas C. Hughes  
Reg. No. 42,674

One Broadway  
New York, New York 10004  
(212) 425-7200